THE HON'BLE MR JUSTICE L. NARASIMHA REDDY

W.P.No.3798, 3799, 3800 & 7451 of 2007

Dated 01-05-2007

Between:

Dr.Ronald Ross Health Society and others

…Petitioners

And

The Director, Drugs Control Administration and others

…Respondents

THE HON'BLE MR JUSTICE L. NARASIMHA REDDY

W.P.No.3798, 3799, 3800 & 7451 of 2007

COMMON JUDGMENT:

In this batch of writ petitions, the action of the Director, Drugs Control Administration of Andhra Pradesh, the 1st respondent,

in proposing to stop the running of Blood Banks by the petitioners, on the basis of the proceedings dated 02-02-2007, issued by the State Blood Transfusion Council, the 2nd respondent herein;

is challenged. The brief facts, that led to the filing of the writ petitions, are as under:

The petitioners are registered voluntary organizations. They have either established, or have taken over the existing Blood Banks at different places in the State. Till recently, it was permissible for any organization, or individual, to establish a Blood Bank, duly complying with the provisions of the Drugs and Cosmetics Act, 1940,

(for short 'the Act'), and the Rules made thereunder.

The studies conducted by the Government of India, reveal that one of the major causes, for spread of AIDS, is the transfusion of contaminated blood, supplied by the Blood Banks. With a view to curb this, the Government of India amended Rule 122-F and 122-G, through a notification, published in GSR 733 (E), dated 21-12-2005, restricting the grant of licences, only those Blood Banks, that are run by the Government and Indian Red Cross Society. Establishment of Blood Banks, either by organizations or individuals, with profit motive is totally prohibited. Hospitals, charitable trusts, or voluntary organizations, which are approved by the 2nd respondent, were permitted to apply for licences.

The Government of Andhra Pradesh constituted Blood Transfusion Council. Much before this, the Government of Andhra Pradesh formulated certain guidelines through its order in G.O.Rt.No.1148, dated 30-10-2001. The petitioners submitted applications to the 2nd respondent for approval, so that they can submit applications for renewal of the licences to the

1st respondent. The 2nd respondent considered the applications, submitted by various applicants, including the petitioners. Through its proceedings, dated 02-02-2007, it refused to accord approval.
It issued no objection certificate, to some of the applicants, and rejected the others, including the petitioners. On the basis of these proceedings, the 1st respondent initiated steps, to prevent Blood Banks from being operated.

The petitioners submit that the 2nd respondent has taken upon itself, the functions of Licensing Authority; whereas, whatever conferred upon it, under the amended Rules; is the power to grant approval. They contend that the parameters for granting approval, on the one hand, and renewal of licences, on the other hand, are totally different.

Heard Sri S. Srinivas Reddy, learned counsel for the petitioners; learned Government Pleader for Medical and Health and Dr.K.Laxmi Narasimha, learned counsel for the 2nd respondent.

The Act and the Rules made thereunder prescribe a detailed procedure, in the matter of granting licence for various activities,
in relation to human blood. It became impermissible for private individuals or agencies, to establish or continue Blood Banks with profit motive, in view of the recent amendments to this. To overcome this prohibition, the Societies came to be formed, and attempts were made to bring about the existing Blood Banks under the purview of the Societies, proclaiming that they are voluntary organizations, functioning without any profit motive.

Till the Rule was amended, it was open to any applicant to directly approach the 1st respondent, either for grant, or renewal of licence, for the Blood Bank. Sub-rule (2) of Rule 122-G, which was

added through amendment; reads as under:

> "Application for grant or renewal of a licence for operation of Blood Bank or processing of Human Blood components shall be made by the Blood bank run by the Government, Indian Red Cross Society, Hospital, Charitable Trust or Voluntary organization approved by a State/Union Territory Blood Transfusion Council only.
>
> *Explanation*: For the purpose of this sub-rule, "renewal" shall include renewal of any licence issued prior to the commencement of the Drugs and Cosmetics (Amendment) Rules, 2005".

In the light of this, it become incumbent for an applicant, first, to approach the 2nd respondent for approval. It is only such agencies, which are accorded approval, that can apply for grant, or renewal of licence.

From the Scheme under the Act and the Rules, it is evident that the verification of technical aspects, in relation to establishment of Blood banks; is the function of the 1st respondent. The nature of verification by the 2nd respondent is limited to the composition of any organization, approval and its method of functioning. The emphasis is to satisfy itself, whether the applicant had any profit motive, or its object is only to serve the people. Obviously, because the exercise is being undertaken, almost for the first time, necessary parameters to be followed, in this regard; do not appear to have been formulated. Naturally this has resulted in overlapping of the functions, as is evident from the impugned order, dated 02-02-2007.

A perusal of the impugned proceedings discloses that the applications were rejected on grounds, which cannot be attributed to the genuine functions of the 2nd respondent. In many cases, no grounds, whatever, were indicated. In other cases, the grounds, which

are totally irrelevant; were stated. In the remarks column, except, "*recommended or not recommended*", nothing was stated. A single order, in a tabulate form, was passed, dealing with all the applications.

When an application is filed for approval, the 2nd respondent is under obligation to examine each application, separately, and record its finding, as to its satisfaction about the eligibility of the applicant. It must be noted that the 2nd respondent cannot embark into the technical aspects, and must concentrate on the constitution and functioning of the applicants.

For the foregoing reasons, the writ petitions are disposed of, directing that the 2nd respondent shall pass fresh orders, on the applications filed by the petitioners, for grant of approval, duly assigning reasons, separately, for each application. It shall also be open to it, to seek any further information from the petitioners, to satisfy itself, about their eligibility. This exercise shall be completed within a period of six weeks from the date of receipt of a copy of this order. Till such time, the 1st respondent shall not take any punitive steps against the petitioners, in relation to the Blood Banks, being run by them, as long as the prescribed standards and norms are followed. In case any deviation is noticed, it shall be open to the 1st respondent to direct closure, or stoppage of the activities.

There shall be no order as to costs.

L. NARASIMHA REDDY, J.

Dt.01-05-2007.

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